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**Standard Operating Procedure**

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| **Number:** | UM/13/SOP/Incident/02/0.1 |
| **Title:** | **SOP for Responding to Research Related Compliance Incidents** |
| **Version:** | 0.3 | **Effective Date**  |   |
| **Author:** | April Lockyer |  |  |
| **Reviewed by: Genevieve Pridham** | **Approved By: April Lockyer** |
| **Position:** Research Governance, Ethics and Integrity Officer (Ethics) | **Position:** Head of Research Governance, Ethics and Integrity |
| **Signature:**  | **Signature:**  |

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| **Version** | **Date**  | **Reason for change** |
| 0.3 | 1/10/2019 | Updates to procedure and contacts |
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**When using this document please ensure that the version you are using is the most up to date either by checking on the Directorate of Research and Business Engagement website (**<https://www.staffnet.manchester.ac.uk/rbe/ethics-integrity/>) **for any new versions or contacting the author to confirm the current version.**

1. **Background**

1.1 The University of Manchester (the University) is a large research intensive organisation with a heavily devolved structure. Its research covers a large breadth of disciplines and a wide geographical area. It is inevitable that research-related compliance “incidents” occur which require investigating and resolving.

1.2 In order to maintain compliance with University policy and data protection legislation the Research Governance, Ethics and Integrity team expect to be informed of all research related incidents that involve a research project conducted by a member of the University’s staff or one of its students or research for which the University acts as sponsor as defined by the UK Policy Framework for Health and Social Care Research. See section 4.0 regarding how to report an incident.

***Definition of Incident:***

1.3 For the purposes of this SOP, “incident” includes, but is not limited to, the following events/happenings in relation to research:

1. A complaint (i.e. from a research participant/fellow researcher/member of the public/donor or donor’s family re anatomy) which relates to the conduct of the research;
2. Substantial deviation from the ethically approved study protocol;
3. An adverse event: an event/happening that has caused unanticipated harm/upset/injury to any individual or the environment as a result of the research;
4. Breach of the principles of good practice, including, but not limited to, good research practice, good manufacturing practice, good laboratory practice and good clinical practice;
5. Breach of the UK Policy Framework for Health and Social Care Research;
6. Breach of any University policies including the [Code of Good Research Conduct;](http://www.staffnet.manchester.ac.uk/services/rbess/governance/conduct/)
7. Breach of any legislation that governs the research.
8. Breach of ethics or HRA and HCRW/R&D Approval;
9. Failure to obtain the necessary approvals for the research;
10. Failure to adhere to professional standards of conduct;
11. Failure to comply with policies and SOPs that govern the research in question;

**2.0 The Purpose of the SOP**

2.1 In some circumstances the University has procedures for responding to specific incidents concerning research such as serious adverse events involving clinical trials, data breaches and research misconduct. This SOP is designed to provide a mechanism for handling and investigating incidents that do not already have a University policy or local SOP to follow and to clarify how and to whom incidents should be reported.

2.2 This SOP should assist a PI or researcher with handling an incident by providing a process for reporting the incident as well as contact details of those who should be notified under specific circumstances and those who can provide help and advice. The purpose is also to provide a process for the investigation of more complex and serious incidents for those staff involved in research governance and ethics.

**3.0 Roles and Responsibilities**

3.1 The University of Manchester’s lead on matters relating to research integrity is the Associate Vice President for Compliance, Risk and Research Integrity.

3.2 The University’s operational lead on matters relating to research integrity is the Head of Research Governance, Ethics and Integrity. S/he is responsible for overseeing the implementation of this SOP and for the co-ordination of all cases handled through the University’s [Code of Practice for Investigating Concerns about the Conduct of Research.](https://www.staffnet.manchester.ac.uk/rbe/ethics-integrity/research-misconduct/)

3.3 The Principal Investigator, or in the case of students their supervisor, is responsible for ensuring that research related incidents are handled appropriately and reported to the appropriate individuals in accordance with any relevant University policies and procedures and this SOP. They are also responsible for responding to requests from the Incident Manager and implementing any recommendations made following the investigation of an incident.

3.4 The Incident Manager is the person who co-ordinates the investigation into an incident, finalises the Incident Report Form and ensures that incidents are appropriately reported, investigated, logged and follow up actions are implemented. For incidents that relate to studies approved by or linked to the University Research Ethics Committees, the Research Ethics Officer will be the Incident Manager. For incidents that relate to studies that are sponsored by the University of Manchester as defined by the UK Policy Framework for Health and Social Care Research, the Research Practice Governance Manager will be the Incident Manager.

**4.0 The Procedure**

**4.1 Recording details of an incident**

4.1.1 If a research related incident occurs, as defined in 1.3 above, the Principal Investigator, or their delegate, or the person who receives details of the incident initially, should gather as much information as possible about the incident and complete the Incident Response Form in Appendix 1. It is important to include dates and details of any medication involved. The PI, or person completing the Incident Response Form should consider whether there is potential for harm to participants, animals, the environment, the researchers or the reputation of the University if the study/data collection continues. Also, s/he should consider whether the data integrity have been affected by the incident. Having considered these issues, the PI should decide whether to suspend the study immediately. If the person initially responding to the incident is not the PI, the Incident Manager should determine whether the research should be suspended.

**4.2 Reporting an incident**

 The incident response form should be sent as soon as possible as follows:

* + If it is a study approved by UREC or by the UREC + HRA it should be sent to the Research Ethics Officer (email research.ethics@manchester.ac.uk).
	+ If it is a study approved by NHS REC only, NHS REC + HRA or HRA only it should sent to the Research Practice Governance Manager (email FBMHethics@manchester.ac.uk).
	+ If it is neither of the above it should be sent to the Head of Research Governance, Ethics and Integrity (email research.compliants@manchester.ac.uk)

The person who receives the report at this stage will be the Incident Manager.

* 1. **Responding to a reported incident**

4.3.1 If there is a University policy or local SOP in place to deal with the specific type of incident (or to be used in conjunction with this SOP), then the incident should immediately be referred to that policy/SOP and the person who oversees that process (some details are provided in Appendix 2). The incident response form should be signed off, logged and filed.

4.2.2 Once the incident has been reported to the Incident Manager s/he may need to devise an Incident Response Plan, together with the study PI in order to investigate the incident answering the following questions:

* Who should be notified/involved?
* How should the incident be investigated?
* What additional information is needed?
* How should this information be obtained?
* How long will it take to obtain the information?
* Should a meeting be scheduled to discuss the incident? Who should be involved? When should the meeting be held?
* Who should be kept informed of progress with the investigation?
* Who will need to be notified about the outcome of the investigation?

Help with devising the plan is provided in 4.3 below.

4.2.3 The incident should be assigned a reference that should follow the format:

* Faculty Initials (i.e. BMH, FSE, Hum)/month/year/initials of Incident Manager
* (The month and year correspond to the date that the incident was reported)
* For example BMH/02/12/AJL
* Where there is an incident with this reference already, the reference should be assigned as follows BMH/02/12/AJL2 and so on.

4.2.4 It may sometimes be necessary to suspend a study/halt data collection while an incident is being investigated if the incident is serious and there is potential for harm to humans, animals, the environment or the reputation of the University. If the Incident Manager has serious concerns about the potential for harm should the study continue they should liaise with the Chair of the Ethics Oversight Committee or Chair of HRA Oversight Committee or the Head of Research Governance, Ethics and Integrity to agree the appropriate actions to be taken.

4.2.5 The Incident Manager should notify relevant individuals about the incident as quickly as possible providing them with the information already collected. The individuals that need to be notified will depend on the nature of the incident and the reporting requirements of the UREC and HRA Oversight Committees. If it is unclear who may need to notified, advice may be sought from the Head of Research Governance, Ethics and Integrity.

4.2.6 Incident response forms completed by the PI/researcher may need to be further amended by the Incident Manager as additional information is obtained or additional individuals outside the team are informed.

**4.3 The Incident Response Plan**

***4.3.1 Who should the Incident Manager notify/involve?***

1. You should consider what other members of the University may need to be notified of the incident and whose advice may need to be sought.
2. Where there is a potential case of research misconduct, the Vice President for Research must be notified and the case referred to the Code of Practice for Investigating Concerns about the Conduct of Research (notification would usually be via the Head of Research Governance, Ethics and Integrity).
3. Where there is potential for reputational damage to the University, the PR Office should be informed as well as the Office of the President and Vice Chancellor and the relevant Faculty Dean.
4. If a complaint is about harassment and bullying the case should be referred to HR, or Student Support Services if it concerns a student.
5. Consideration should be given to what third parties should be informed. For example, where the research is being undertaken on premises other than a University site (such as an NHS Trust). An ethics committee may also need to be notified.

***4.3.2 How should the incident be investigated?***

1. If the Incident Manager becomes concerned at any point that there is potential misconduct on the part of anyone involved in the incident s/he should report these concerns to the Head of Research Governance, Ethics and Integrity or the Vice President for Research in his/her absence.

***4.3.3 What information is required?***

1. The Incident Manager should decide what information is required and how this information is best obtained. This may include documentary evidence and witness observations. Individuals should be given tight deadlines to provide information in relation to the investigation of the incident with a view to the investigation being completed within 5 days of it being reported to the Incident Manager.

What information is needed is dependent on the incident itself. However, in general the Incident Manager will need to understand the research project and details regarding how the research project should have been conducted. In general, the Incident Manager should request the research protocol, details of ethical approvals, consent forms, standard operating procedures, questionnaire, interview schedule and participant information sheets.

***4.3.4 How should this information be obtained and how long will it take?***

The Incident Manager should consider how long it will take to investigate an incident and try to keep this time to a minimum. S/he should consider the necessity of receiving information against the time it would take to obtain it. Thought should be given to obtaining information in both a sensitive as well as an efficient way.

***4.3.5 Should a meeting be scheduled to discuss the incident?***

1. If an incident is complex and involves several people it may be quickest to arrange a meeting in order to ascertain the facts.
2. Alternatively, a meeting may be necessary at the end of the process in order to discuss the findings of the investigation and any recommended changes and improvements in practice for the study team.

***4.3.6 Who should be informed of progress/notified of the outcome***

The Incident Manager should keep all involved parties informed of progress with the investigation. S/he should check if there are any contractual/regulatory requirements to inform any third parties about the incident, the investigation of the incident or the outcome of the incident. S/he should notify such parties and keep them informed as appropriate.

**4.3.7 Support and Guidance**

The Incident Manager can receive support and guidance at all times from the Head of Research Governance, Ethics and Integrity.

**4.3.7 The Investigation**

The Incident Manager will check the documentation gathered against the approved study documentation and any related University policies and procedures or regulatory requirements to determine if there are any gaps between expectations and delivery. The Incident Manager should maintain a record of his/her deliberations and conclusions which should be summarised at the end of the Incident Response Form.

**4.4 Incident outcome**

When the investigation has been completed and final actions agreed, the Incident Manager will notify all interested parties of the outcome. This would usually be via the completed Incident Response Form.

Where there are actions that need to be implemented, these should be implemented before the Incident Response Form has been signed off unless the actions are policy-related for the University.

1. **Recording and monitoring**

All incident reports will be filed with the Incident Manager.

The Incident Manager should include details in their quarterly report to the Research Compliance Committee as appropriate.

Records of incidents should be retained for 7 years. Care should be taken regarding confidentiality and data protection. **Appendix 1**

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**Incident Response Form**

**To be completed by the PI/researcher and/or a member of the Incident Response Team**

**Reference:**

(Completed by Incident Manager)

**Date:**

**Initial response completed by:**

**Incident Manager:**

|  |  |
| --- | --- |
| Type of incident  | Choose an item. |
| Name of PI and other relevant researchers involved |  |
| Full title of study |  |
| NHS REC Reference (if applicable) |  |
| UREC Reference (if applicable) |  |
| IRAS number (if applicable) |  |
| Eudract No. (if applicable) |  |
| Name and contact details of person reporting the incident |  |
| Date incident occurred and date incident reported to the research team, if different.  |  |
| Location incident took place |  |
| Research Governance Sponsor (UK Policy Framework - if applicable) |  |
| Details of the incident (including names or, the case of participants, pseudonyms / study IDs of those involved) |  |
| Actions already taken to deal with the incident |  |
| Details of who have already been notified of the incident |  |
| What other organisations are involved and the contact people at those organisations if possible |  |
| **Signature of PI** | **To be completed before sending to the Incident Manager** |
| Signed  |  |
| Dated |  |
| **OFFICE USE ONLY****For completion by Incident Manager** |  |
| Additional Details |  |
| Details of additional individuals notified |  |
| Evidence collected |  |
| Details of investigation |  |
| Actions taken |  |
| **For breaches of ethics/adverse events** |  |
| Clarify the procedure that should have been followed as outlined in the ethics approval and details of specifically where any deviations or incidents occurred. |  |
| **Outcomes** |  |
| Further action(s) to be taken by the PI |  |
| Timeframe for actions to be taken | Choose an item. |
| Further individuals to be informed by the PI |  |
| Final outcome  | Choose an item. |
| Issues raised with broader implications for policy (if applicable) to be reported to RCC. |  |
| **Signature of Incident Manager** | **To be completed once the incident is referred to another team or resolved** |
| Signed |  |
| Dated |  |

**Appendix 2**

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| **Local Incident Policy/SOP** | **Type of Incident** |
| [Research Misconduct](https://www.staffnet.manchester.ac.uk/rbe/ethics-integrity/research-misconduct/research-misconduct/) | * Potential research misconduct
* Governance/good research practice
 |
| [UREC Complaints, Breaches and Appeals Procedure](http://documents.manchester.ac.uk/admin/EditDoc1.aspx?DocID=23705) | * Breaches of UREC approval
* Adverse events (UREC studies)
* Complaints
 |
| [HTA Adverse Event/Incident Reporting](http://documents.manchester.ac.uk/display.aspx?DocID=8612%20) | * Incidents involving human tissue (all Faculties)
* Adverse events (human tissue)
 |
| [Reporting a Serious Breach](http://documents.manchester.ac.uk/display.aspx?DocID=11005%20) | * Incidents involving a clinical trial (all Faculties)
* Adverse events (clinical trials)
 |
| [Incident Reporting](https://www.staffnet.manchester.ac.uk/bmh/research/ethics-and-regulatory-support/reporting-requirements/) | * Breaches of HRA approval (all Faculties)
* Adverse events (HRA studies)
* Incidents involving FBMH
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| Contact the AWERB Secretary: AWERB.Secretary@manchester.ac.uk | * Breaches of AWERB approval
 |
| [Reporting Data Protection Incidents](https://www.staffnet.manchester.ac.uk/igo/data-protection/report-data-protection-incident/) | * Incidents involving data security
* Incidents involving personal data
* Data breaches
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